REMARKS

The Invention

The invention is directed to an adhesive composition comprising from about 50- to about 98 % by weight of an alkyl acrylate monomer and/or alkyl methacrylate monomer and from about 2 to about 50% of a polymerizable non-cyclic nitrogen-containing monomer. The claimed adhesive lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker. What is meant by "reactive hydrogen moieties" and "post-polymerization chemical crosslinker" is defined on page 5 of applicants' specification. The invention is also directed to transdermal drug delivery systems comprising the adhesive and to methods of treatment using the transdermal systems of the invention.

Double Patenting rejection and Section 102 (e) rejection over U.S. Patent No. 6,077,527 (Tan *et al.*)

Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,077,527. The examiner urges that the claims of the instant application and the issued patent are not patentably distinct since both claim an adhesive composition comprising alkyl acrylate monomer and/or alkyl methacrylate monomer and nitrogen containing monomer.

Claims 1-11 and 14 are rejected under 35 U.S.C. § 102 (e) as being anticipated by U.S. Patent 6,077,527 ('527). U.S. Patent '527 is cited by the examiner as disclosing a pressure sensitive adhesive composition for use in transdermal drug delivery devices comprising at least 40 % by weight of alkyl acrylate including n-butyl and 2-ethylhexyl acrylate, and 10-60% by weight of substituted acrylamide, or (meth)acrylamide including t-octyl acrylamide. The examiner urges that

applicants' claimed Tg is inherent for the particular composition.

Applicants respectfully disagree.

The '527 patent does not disclose an adhesive composition that lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker. The examiner is referred to col. 2, lines 49-50, wherein use of acrylic acid and vinyl monomers such as vinyl acetate, which contain functional groups, are described for use. See also col. 4, lines 17-27. Moreover, the '527 patent requires the use of a crosslinker (see col. 4, lines 28-31) that cannot be used in the practice of applicants' invention. In order to use the aluminum or titanium crosslinker described in the '527 patent, need acrylic monomer that contains a reactive group. The disclosure of the '527 patent is concerned with problems associated with use of penetration enhancers in adhesives used in transdermal systems, and is directed to adhesives tolerant to plasticization by penetration enhancers used in transdermal systems. In contrast, applicants' invention is concerned with problems associated with the reactivity of drugs with adhesives used in transdermal systems, and is directed to non-reactive adhesives, i.e., adhesives that do not contain a reactive hydrogen or any post-polymerization chemical crosslinking.

Applicants' claimed invention is not anticipated by '527.

Withdrawal of the obviousness-type double patenting rejection and the Section 102 rejection is requested.

Section 102 (e) rejection over U.S. Patent Application Publication No. 2002/0150613A1 (Govil *et al.*)

Claims 1-6 and 8-14 are rejected under 35 U.S.C. § 102 (e) as being anticipated by PGPUB 2002/0150613 ('613). This document is cited by the examiner as disclosing a transdermal drug

delivery device comprising a backing layer, a release liner and an adhesive layer comprising the drug, the adhesive layer comprising 40-90 % by weight of alkyl acrylate including n-butyl acrylate and 2-ethyhexyl acrylate and 15-30% by weight of monomer selected from (meth)acrylamide, N-butyl-acrylamide or (meth)acrylonitrile. The examiner urges that applicants' claimed Tg is inherent for the particular composition.

Applicants respectfully disagree.

The '613 disclosure is concerned with adhesives for use with highly plasticizing drugs. The described adhesviescontain between about 1% and about 15% by weight of a functionalizing monomer which facilitates crosslinking and may include a crosslinking agent (see paragraph [0024], lines 10-12). The examiner is also referred to paragraph [0028].

Applicants' claimed invention is not anticipated by '613.

Withdrawal of the Section 102 rejection is requested.

Section 102 (e) Rejection over U.S. Patent No. 6,132,760 (Hedenstrom *et al.*)

Claims 1-6 and 8-14 are rejected under 35 U.S.C. § 102 (e) as being anticipated by U.S. Patent 6,132,760 ('760). U.S. Patent '760 is cited by the examiner as disclosing a transdermal drug delivery device including an adhesive layer containing an active ingredient, a backing layer and a release liner. The adhesive layer comprising 45-95 % by weight of alkyl acrylate including n-butyl acrylate, 2-ethylhexyl acrylate and methacrylate and 5-55% by weight of sustituted acrylamide, acrylonitrile, (meth)acrylonitrile and vinyl acetamide. The examiner urges that applicants' claimed Tg is inherent for the particular composition.

Applicants respectfully disagree.

The '760 patent is directed to a transdermal device for the delivery of testosterone. Preferred adhesives are acrylate copolymers comprising one or more A monomers and one or more B monomers (see col. 2, lines 47-48 to col. 3, lines 1- 28). Suitable B monomers include those comprising a functional group. Exemplified monomers include, e.g., acrylic acid and hydroxylalkyl acrylate, which cannot be used in the practice of the invention.

Applicants' claimed invention is not anticipated by '613.

Withdrawal of the Section 102 rejection is requested.

Section 103 rejections over any of U.S. Patent Application Publication No. 2002/0150613A1, U.S. Patent No. 6,132,760 or U.S. Patent No. 6,077,527

Claims 1-11 are rejected under 35 U.S.C. § 103 as being unpatentable over any of the '613, '760 or '527 documents.

The examiner urges that while '613 and '760 do not teach the species of acrylamide (t-octyl acrylamide) and '527 does not teach the backing layer or release liner of the transdermal device, it is within the skill of the art to replace one species by another or genus by species known to perform similar functions. In particular, the examiner urges that it would have been obvious to replace the substituted acrylamide of '613 or '760 by t-octyl acrylamide. The examiner further urges that no criticality has been shown in using t-octyl acrylamide in particular.

Applicants respectfully disagree.

None of the '613, '760 or '527 documents disclosure or even suggest an adhesive useful in transdermal drug delivery systems lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker. There is nothing in the '613, '760 or '527

disclosure that would motivate the skilled artisan to select the components required for use in the practice of applicants' claimed invention.

Withdrawal of the Section 103 rejections is requested.

Conclusion

The claimed invention represents a valuable and patentable contribution to the art.

Favorable reconsiderationand allowance of claims 1-14 is solicited.

Respectfully submitted,

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Version of claim showing changes made

1 (amended). An adhesive composition [which lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker] comprising, on a dry weight basis, from about 50 to about 98% of an alkyl acrylate monomer and/or alkyl methacrylate monomer and from about 2 to about 50% of a polymerizable non-cyclic nitrogen-containing monomer, wherein said composition lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker.